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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION**

N8 MEDICAL, INC.,  Plaintiff,  v.  COLGATE-PALMOLIVE COMPANY,  Defendant.	<b>REPLY IN FURTHER SUPPORT OF MOTION TO JOIN BRIGHAM YOUNG UNIVERSITY PURSUANT TO FRCP 19</b>  Case No. 2:13-cv-01017  Judge Bruce S. Jenkins
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Plaintiff N8 Medical, Inc. ("N8 Medical"), respectfully files this Reply to Defendant Colgate-Palmolive Company's ("Colgate") Memorandum in Opposition to N8 Medical's Motion to Join Brigham Young University Pursuant to FRCP 19 ("Colgate's Opposition").

**A. BYU Has Moved to Intervene.**

On February 20, 2014, BYU filed a motion pursuant to FRCP 24 to intervene in this matter. [Dkt. 56] BYU seeks permission to intervene for the very reasons that N8 previously sought to join BYU under Rule 19. BYU has a substantial interest in the litigation that is closely inter-related with N8's dispute with Colgate. BYU has provided compelling reasons why its interest may be adversely impacted if BYU is not present as a party. Finally, BYU demonstrates that N8 cannot adequately represent or protect BYU's interest in the litigation. The Court should grant BYU's request to intervene or alternatively grant N8's motion to join BYU in this lawsuit.

**B. The Court Should Join BYU in this Litigation.**

In order to determine if BYU should join the litigation, the Court must determine if BYU is a required party under Rule 19. A required party includes a person who claims an interest relating to the subject matter of the action and is so situated that disposing of the action in the person's absence may as a practical matter impair or impede the person's ability to protect the interest. Rule 19(a)(1)(B)(i). Here, BYU is a required party.

**1. BYU is a Third Party Beneficiary of the MTA.**

When Colgate and N8 negotiated and executed the MTA which lies at the heart of N8's claims against Colgate, they recited that N8 has an exclusive license from BYU to develop and sell proprietary ceragenins in fields of application relevant to Colgate's interest. See MTA at Recital 1 attached hereto as Exhibit 1. In light of this fact, Colgate and N8 expressly named BYU as a third party beneficiary of the MTA. See Ex. 1 at ¶ 27. ("The parties agree that they are voluntarily entering into this Agreement for the express benefit of BYU...") As a third party beneficiary, it is clear that BYU has an interest relating to the subject matter of this action.

**2. BYU Claims an Interest Relating to the Subject Matter.**

The 10th Circuit has held that Rule 19 does not require that an absent person actually possess an interest; it only requires that a movant show that the absent party *claims* an interest relating to the subject of the action. *Davis v. United States*, 192 F.3d 951, 958 (10th Cir. 1999). After N8 filed its motion to join BYU as a necessary party, BYU filed a notice of non-opposition to the motion [Dkt. 38] and confirmed that it has an interest in the subject matter of the dispute.

**3. BYU's Interest May be Impaired or Impeded.**

Colgate admits that BYU is interested in the litigation, i.e. that BYU has legally protectable interests in this litigation. However, Colgate argues that to join BYU, the Court must find that BYU's rights "will be impaired." Opp. at 15. Rule 19 requires no such finding by the Court. Rather, Rule 19 provides that a person must be joined if disposing of the action in that person's absence "**may: (i) as a practical matter** impair or impede the person's ability to protect the interest." FRCP 19(a)(1)(B)(i).

BYU has an undisputed interest in the misuse and impairment of its intellectual property by Colgate. N8's and BYU's claims both arise out of the MTA, which provides for the transfer and evaluation by Colgate of BYU's property (e.g., ceragenins, including CSA-13 and CSA-44). Ex. 1 at p.1. The MTA specifically prohibits Colgate from using the ceragenins for commercial purposes. Ex. 1, Sec. 1. The MTA provides that any improvement that incorporates the ceragenins license by BYU to N8 is a Joint Invention of Colgate and N8. Ex. 1, Sec. 7(b)(3). Colgate could not seek patent protection for inventions involving ceragenins without first notifying N8 and complying with other applicable provisions of the MTA. Ex. 1, Sec. 7(b)(4). Colgate obtained no rights in these ceragenins outside the terms of the MTA, which prohibited the exact conduct in which Colgate engaged. Ex. 1, Sec. 7(a).

N8 alleges, and it is beyond dispute, that Colgate prepared and filed a PCT and several other patent applications (the “Unauthorized Filings”) in at least four (4) jurisdictions outside the United States seeking patent protection for claims that incorporate the ceragenins provided by N8 to Colgate under the MTA. See PCT attached hereto as Exhibit 2. These Unauthorized Filings disclose to the world the nature of many ceragenins, their chemical makeup, their properties, and potential uses. This disclosure adversely impacts N8 because N8 holds the exclusive license from BYU to the compounds for oral mouthwash and mouth rinse.<sup>1</sup> It affects BYU’s interests in the compounds for fields of application not licensed to N8.

The Unauthorized Filings have been published as a result of the wrongful disclosure by Colgate of the compounds and the data and properties set forth therein. If approved, and patents issue, the time period during which the patents provide protection for the claims begins to run – in this case prematurely, well before the timing intended by N8 or BYU. Thus the timing of the filing of the patent application (more than 3 years ago), and the timing of the issuance of the patent, impact the period of time a patent owner has to commercialize its patented ideas free of competition. The impact of the Unauthorized Filings on N8 relates to the mouthwash and other applications for which it has been licensed by BYU. The impact to BYU is broader and implicate additional fields of application outside of the N8 license.

**a. BYU’s Patent Rights are Affected.**

Colgate claims that BYU has not articulated an interest related to the subject matter that may be impaired or impeded by this lawsuit. That assertion is without basis. To illustrate the interests that BYU has that may be impaired or impeded in its absence, the Court can look at

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<sup>1</sup> See First Amended Exclusive License Agreement between Brigham Young University and N8 Medical, Inc. attached hereto as Exhibit 3.

Colgate's unauthorized PCT and BYU's license to N8 Medical. The Colgate PCT lists certain claims for which it seeks patent protection. Ex. 2 at 15, 17. Colgate's PCT described various methods of treating diseases or conditions of the oral cavity. Colgate's PCT does not limit those claims to human applications. N8 Medical does not hold a license to fields of application related to (non-human) animals. BYU owns those fields of application and may have licensed them to others. Since N8 Medical does not own this interest through its BYU's license, N8 cannot protect BYU's interest in this litigation.

As BYU alleges in its Motion to Intervene, BYU has actively sought to protect its ceragenin intellectual property through a coordinated strategy that includes, in part, a series of past, present, and future patent applications that would maintain and continue patent protection in multiple fields of use beyond existing patents. Premature filing of patent applications outside that coordinated effort could jeopardize the ability of BYU to maximize patent protection of this intellectual property across all fields of use because such applications are sometimes viewed as "prior art" that interferes with the ability of others to obtain a patent on related subject matters. The wrongful actions of Colgate may have caused enormous problems for BYU in connection with protecting its intellectual property licensed to N8 Medical in certain fields.

**b. Claim Preclusion May Impair or Impede BYU's Interests.**

BYU is in privity with N8 due to the exclusive license and BYU's status as a third party beneficiary of the MTA. If Colgate and N8 litigate to final judgment, the risk to BYU of issue preclusion is significant. *Oman v. Davis Sch. Dist.*, 2008 UT 70, ¶ 28, 194 P.3d 956, 965 (citing *Buckner v. Kennard*) ("Issue preclusion, which is also known as collateral estoppel, prevents parties or their privies from relitigating facts and issues in the second suit that were fully litigated in the first suit."). The Court can reasonably anticipate that issues decided in this case (use of

materials, testing protocols and results, communications, disclosure and non-disclosure, timing and effect of patent applications, knowledge of parties' interests, etc.) may be identical to those presented in a later action by BYU. In the present litigation, one may reasonably anticipate that these issues will be completely, fully, and fairly litigated among N8 and Colgate limited as they likely will be by their respective interests and relevancy considerations. BYU may face collateral estoppel arguments if it is not joined in this action. Because collateral estoppel arguments may as a practical matter impair or impede BYU's interests, joinder under Rule 19 is appropriate.

**c. N8 Cannot Adequately Protect BYU's Interest.**

Colgate claims that BYU's interest in this litigation is virtually identical to N8's and for support relies on *Sac and Fox Nation of Missouri v. Norton*, 240 F.3d 150 (10th Cir. 2001). Colgate's assertion ignores that BYU's interests, as discussed above, are not virtually identical to N8's. BYU's interests and N8's interests here are aligned but not identical. Unlike in *Norton*, N8 does not have the right or standing to argue on behalf of BYU for protection of ceragenins in fields of application for which BYU owns and N8 does not have a license. While N8's exclusive license has been harmed by Colgate's flagrant disregard of its contractual commitments, those license rights are not "virtually identical" to BYU's ownership interest in the compounds which includes the compounds, all of its licensees of those compounds, and all fields of application including those fields not licensed to N8. Moreover, unlike the Wyandotte Tribe in *Norton*, BYU has not been heavily involved in this action. Thus, its interests have not been fully vetted and protected in motions and other filings with the Court. In this case, a multitude of factual issues exist and may arise during the litigation that not only affect N8 and Colgate but also BYU. If BYU is not present in the litigation, it could nevertheless be bound by the determination of those issues.

Colgate argues that BYU gave N8 the right to pursue independently actions for misuse. But this contractual provision in N8's exclusive license does not confer on N8 standing to pursue claims against Colgate for which N8 is not a licensee or that N8 does not legally own. Thus, while BYU's grant of authority to N8 to pursue claims of misuse is interesting, it is a red herring and ignores that the clause referenced specifically contemplates joining BYU. Similarly, BYU's and N8's agreement to obtain approval for settlement does not imbue N8 with authority to pursue claims on behalf of BYU that do not arise from N8's license from BYU. N8 may make *some* of the arguments BYU would make in this case, but not all. N8 is not the ultimate owner of the compounds, does not have access to BYU's entire patent portfolio or its business plans for its entire patent portfolio for all fields of use, and does not have sufficient information about BYU's other licensees whom BYU may seek to protect in this litigation. See, *Wright v. Incline Village General Improvement District*, 597 F.Supp.2d 1191, 1208 (D.NV 2009) (holding that under Rule 19(a)(1)(B), where an absent person may have interests that may not be raised by an existing party, those interests may not be adequately protected by the existing party.)

#### **4. The Assignment Does Not Moot the Harm to N8 or BYU.**

Colgate argues that assignment of the Unauthorized Filings to N8 moots any harm related to its breaches. Colgate's argument is incorrect. Even though it assigned the Unauthorized Filings to N8, Colgate agreed in the MTAs that it remains liable for all damages caused to N8 by its Unauthorized Filings.<sup>2</sup> Paragraph 7(b)(7) of both MTAs states that even after assignment to N8,

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<sup>2</sup> Colgate's assignment of the Unauthorized Filings to N8 confirms Colgate's violations of the MTAs because Colgate was only required to assign the Unauthorized Filings to N8 if they constituted an unauthorized use of the Materials under the MTAs. *Id.* Further, Colgate ignores that BYU's and N8's ability to mitigate, defend claims made in, make new or additional filings and claims around the subject matter of, and plan the ceragenin patent portfolio around, the

Colgate “**shall** (a) remain liable for any claims, damages or liability of any kind due to [Colgate’s] unauthorized use of the materials and (b) indemnify and hold N8 harmless from any liability resulting from [Colgate’s] unauthorized use of the Materials as set forth in Section 10.” Ex. 1, Sec. 7(b)(7). N8 has made claims for significant monetary damages for, among other claims, Colgate’s failure execute a license agreement with N8 and pay N8 a royalty.

In addition, both N8 and BYU are still harmed by inadequacies in the data and claims disclosed in the Unauthorized Filings, and prior art created. For example, the Unauthorized Filings do not represent an exhaustive effort to capture intellectual property in the disclosed anti-inflammatory and oral care fields. Nor is the compound or activity disclosure contained in the Unauthorized Filings ideal because they are narrow and not exhaustive. As a result, even with the assignment, there will likely be a loss of some intellectual property between the PCT and other current or anticipated patents. Since BYU owns this intellectual property, the loss will be suffered by BYU in a materially different manner than N8 Medical. Moreover, the Unauthorized Filings may constitute prior art in those jurisdictions that will claim priority over BYU is subsequently filed or anticipated patents.

##### **5. Joining BYU as a Party.**

Finally, Colgate misinterprets N8’s motion. Colgate assumes that N8’s motion seeks joinder of BYU as a plaintiff. It cites *Hicks v. International Acceptance Corp.*, 154 F.R.D. 134, 1994-2 Trade Cases P 70,751, 29 Fed.R.Serv.3d 557, to contend that N8 has not met the burden to show joinder of BYU as a party plaintiff is appropriate. But *Hicks* merely acknowledges the proposition that the law disfavors **forced** joinder of party plaintiffs. In *Hicks*, the plaintiff sued

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Unauthorized Filings and disclosures therein, is very limited due to the lack of access to, and withholding by Colgate, of substantial relevant data regarding the subject matter.



creditors and sought joinder of the FTC, an agency of the federal government, as a party plaintiff. The court held that plaintiff failed to establish two of the required elements to require joinder as a party plaintiff under Rule 19.

Rule 19(a) of the Federal Rules of Civil Procedure describes the joinder of parties necessary for just adjudication. ‘If the person should join as a plaintiff but refuses to do so, the person may be made a defendant, or, in a proper case, an involuntary plaintiff.’ Fed.R.Civ.P. 19(a). In this action Plaintiff seeks to join the Federal Trade Commission as an involuntary plaintiff.” *Hicks v. International Acceptance Corp.*, *supra*. In discussing the factors this Court should consider in determining whether to join an involuntary plaintiff, it held that *Hicks* did not make a proper showing. “In this case, Plaintiff has failed to satisfy two of the conditions necessary to establish a ‘proper case’ for joinder.

*Hicks v. International Acceptance Corp.*, 154 F.R.D. at 135.

Here, N8 is not seeking to make BYU a plaintiff against its will. BYU, has in fact sought to intervene. Further, N8 has not sought to join BYU as a party plaintiff. Rather, N8 has moved to join BYU *as a party* under Rule 19 and *suggested* that once joined BYU may be realigned as a plaintiff since its interests are more aligned with N8. But N8 has left it to the Court’s discretion and inherent power to join BYU as a party defendant under Rule 19 and realign the parties at that juncture as it sees fit. See *Hooker Chemicals & Plastics Corp. v. Diamond Shamrock Corporation*, 520 F.Supp.204, 206 (W.D.N.Y 1981).

### **Conclusion**

In summary, Plaintiff N8 respectfully requests that this Court grant its Motion to Join BYU as a party and award it all other and just relief.

Respectfully submitted this 21<sup>st</sup> day of February, 2014,

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